



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER AND PROBE
ESTABLISHMENT NAME	CYPRESS MEDIC SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC6997520-40138
BRAND NAME	ROSSMAX
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Rossmax Pulse Oximeter is used to measure arterial oxygen saturation (%SpO2) of hemoglobin and pulse rate, an important indicator of respiratory function. The model of pulse oximeter, only for SA300, has an ACT analysis function. ACT (Artery Check Technology) analyzes the pulse and SpO2 signals and determines the actually prevailing stiffness of the artery (Artery Condition). It further classifies the vascular status into 6 levels. Rossmax probe combined with pulse oximeter is to spot-check oxygen saturation in blood (SpO2) and pulse rate.
DEVICE INTENDED PURPOSE	SA Series: Rossmax Handheld Pulse Oximeter is used to measure oxygen saturation in blood(SpO2) and pulse rate, also to issue warnings immediately. The model of handheld pulse oximeter, only for SA300, has an ACT (Artery Check Technology) analysis function that analyzes the pulse and SpO2 signals and determines the actually prevailing stiffness of the artery (Artery Condition). It is a non-invasive device intended for spot-check of adults,child, and infants with corresponding probe applied at home, hospital and clinics. The probe contains a dual light source and a photo detector. Probe: The probe combined with pulse oximeter is to spot-check oxygen saturation in blood(SpO2) and pulse rate. The different probes combined with pulse oximeter is used on adults, neonatal, pediatric at hospital, clinics, and/ or home.
VALIDITY DATE OF REGISTRATION	06/01/2020 - 05/01/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	SA210
2	Pulse Oximeter	SA310
3	Pulse Oximeter	SA300
4	Probe	PA100
5	Probe	PB100

NO	NAME OF DEVICE	IDENTIFIER
6	Probe	PC100
7	Probe	PD100
8	Probe	PF100

